General Requirements for the Competence of Air Source Emission Testing Bodies

Draft Proposal

Submitted by
The Air Source Emission Task Team
A sub-committee of
The Environmental Laboratory Advisory Board

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Note:
This document is an unfinished work product and does not yet represent the consensus view of ASETT.

Portions of the NELAC standards are reprinted from ISO/IEC Guide 25:1990, ISO/IEC Guide 58:1993, and ISO/IEC Standard 17025:1999, with permission of the American National Standards Institute.

ISO/IEC Guide 25:1990 has been superseded by ISO/IEC Standard 17025.

Acknowledgements

I would like to acknowledge the participation of many groups in the ASETT process. The issue of stack testing accreditation affects a broad cross-section of stakeholders and ASETT would not have been able to achieve the progress it has without the active participation of many in these groups.

The U.S. Environmental Protection Agency, particularly the Emission Measurement Center, has provided much valuable input as we have moved forward in this process. The National Environmental Laboratory Accreditation Conference (NELAC), in the person of Jeanne Hankins, has been very patient in responding to questions about NELAC structure and function.

State and local agency participants included South Coast Air Quality Management District, Florida, Pennsylvania, Maine, New Hampshire, Illinois, Arizona, Virginia, New Jersey, and Louisiana. This state participation has been particularly valuable since those participating have direct knowledge of stack testing and the unique problems it presents.

Industry participants included the Utility Air Regulatory Group (UARG) a national association of electric utilities, the Florida Co-ordinating Group (a Florida association of utilities), and the American Chemistry Council (formerly the Chemical Manufacturer's Association). Individual companies such as CONSOL Energy, DuPont, Florida Power and Light, Owens Corning and others have actively participated in the process.

Finally, the contribution of many in the stack testing industry has been invaluable. This industry is made up almost exclusively of very small businesses. For those companies to take the time to attend meetings and teleconferences and to review documents has meant either lost business or extra hours. Your participation is deeply appreciated.

While there are still issues to be resolved, we have made substantial progress. As the ASETT process continues we will move ever closer to consensus and a final standard that meets the needs of all stakeholders.

Scott Evans
ASETT Chair

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Introduction

In June of 2000, the Environmental Laboratory Advisory Board (ELAB), a duly authorized Federal Advisory Committee, established a sub-committee to develop a standard of performance and accreditation for testing bodies engaged in air source emission measurement. This sub-committee known as the Air Source Emission Task Team (ASETT) consists of federal and state regulatory officials, industry representatives, and stack testers. ASETT held its first meeting in Research Triangle Park, NC on June 14-15, 2000. At that meeting ASETT established the following purpose and general principles to guide their work on this standard.

Statement of Purpose

- To develop voluntary, objective performance criteria for establishing an acceptable quality standard for air emission testing and sampling.
- To establish consistency in such standards among states.
- To develop objective procedures to determine if the processes are in place to routinely meet that standard.
- To accomplish the above in a manner that minimizes the regulatory and economic burden on all stakeholders.

General Principles of the Standard

The following general principles will be followed in the final standard developed by this group.

- Based on standard methods and existing recognized standards
- Uniform, performance-based criteria
- Allow for innovation, creativity, competition
- Separate performance standards from performance assessment
- Refrain from prescription
- Emphasize quality personnel
- Define “Who pays?”
- Be more educational than prescriptive
- Maintain flexibility in implementation
- Create a level playing field
- Focus on the business process (six sigma)
- Balance quality vs. cost
- Minimize regulatory burden
- Accommodate all sizes and types of businesses
- Maximize uniformity between states
- Define accreditation/disaccreditation procedures
- Recognize shared responsibility for data quality including field operations
- Emphasize documentation of a quality system
- Include an ethics component

There was also general agreement that this standard would be developed a stand-alone document, separate from existing NELAC standards for water laboratories. This is necessary since the philosophy of accreditation followed by ASETT differs markedly from that followed during the development of the water lab standards.

The remainder of this Introduction is devoted to background information on the standard and its implementation.

This Standard

This is a performance-based standard. It establishes performance objectives for a testing body but does not dictate the means to achieve these objectives. For example, Section 5.2.1 on Personnel states:

> "...management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports..."

This clearly states the standard of performance expected. But each testing body will establish their own policies and procedures for how this objective will be accomplished. Whether a testing body has accomplished the objective, is determined by performance data. This could take the form of customer feedback, state agency observer feedback, or internal audit feedback. If such feedback indicates a quality system problem (e.g. poor field performance, invalid data) resulting from poorly trained personnel, the testing body must initiate a corrective action.

A performance-based approach allows each testing body to find the most efficient means to achieve the performance objectives specified in this standard.

The Quality System

This standard establishes a quality system that, if implemented in its entirety and allowed to operate, is self-correcting. In summary, the process works like this:

Test ---> Gather performance feedback ---> Evaluate ---> Adjust the system ---> Repeat

It is a system that results in a continual improvement of performance.

As stated above, this standard establishes performance objectives but it is left to each testing body to determine the best way to meet these objectives. The quality plan required under this standard is the testing body's statement on how it plans to meet the objectives. Conformance with this standard is determined by conformance with this quality plan.

The complexity and formality needed in the quality system depends on the testing body. The stack testing industry is made up almost exclusively of very small companies (<10 people). In companies of this size, informal mechanisms for training, document control, etc. may be very effective. In larger companies with dozens of people and multiple locations, a more formal program may be appropriate. An effort was made to structure the standard so as not to penalize testing bodies with effective informal systems. The emphasis is on performance, not paperwork.

The Role of the Assessor

Once a testing body makes the commitment to meet the objectives stated in this standard, it is responsible for monitoring its continuing conformance. This may be done with internal assessors, and, if the testing body is part of an accreditation program, external assessors. This standard

establishes the objectives to be achieved. HOW each testing body plans to achieve these objectives are stated in the company's quality plan. Each company is assessed against conformance with their own quality plan.

Given the self-correcting nature of a properly implemented quality system, the role of the assessor is to ensure the quality infrastructure is in place and is followed. If there are deficiencies in that infrastructure, they will be revealed by the performance data.

The assessor's role in implementing this program is different than in traditional ISO assessment. Under this standard:

It IS the role of the assessor to:

1) Verify that all required components of the quality system are present
2) Verify that the quality system is working -- that is, performance data is generated and evaluated and corrective steps are taken when problems are found.

It IS NOT the role of the assessor to:

1) Judge the effectiveness of the quality system -- the performance data will determine this.
2) Judge whether a company is "technically competent" -- technical competence of a company can only be determined by consistent performance over time (see below).

The objective of any quality system developed under this standard is the consistent production of quality data -- that is, data that meets the needs of its intended use. The only way that the effectiveness of the quality system can be determined is by evaluating the output of the system -- performance data (defined above). This standard contains explicit instructions to assessors limiting their ability to pass judgement on the effectiveness of the quality plan in the absence of performance data. The assessor must assume that any policy or procedure implemented by a testing body is effective unless there is performance data indicating otherwise. This should dramatically reduce the paperwork burden for small testing bodies.

What Does Accreditation Mean?

A testing body accredited to this standard, has demonstrated to an independent third party (the accrediting authority) that they have implemented all the elements of the quality system required under this standard. They have committed to producing quality data and have a quality infrastructure in place capable of delivering on that promise.

In order to meet the performance objectives established in this standard, technical competence is required for any project the testing body undertakes. However, accreditation does not say anything about the technical competence of the testing body to perform specific test methods. The quality system established by this standard requires testing bodies to evaluate each offer they receive to perform testing. If the testing body determines that it does not have the technical competence to perform the scope of testing offered, they are obligated not to accept the offer. The quality system provides feedback that speaks to the ability of a testing body to accurately evaluate the resources at its disposal at a given point in time and make the proper go/no go decision on a project. The quality system also provides feedback to identify incorrect decisions (determined by performance failure) and minimize the chance of their recurrence.

While it may be possible to make meaningful statements as to the overall technical competence of a person, it is not so straightforward to make these statements with regard to a company. A company is nothing more than an organizational structure for deploying resources to fill a market need. A company has no intrinsic skills or knowledge. The ability of a testing company to deliver adequately trained personnel and other resources varies from day to day sometimes hour to hour. It varies with job scheduling, equipment allocation, vacations, employee turnover, availability of outside resources (contract personnel, rental equipment, etc.), effective communication with regulatory agencies and source operators, the nature of the source parameters and gas matrix, and many other variables.

In short, it is never possible for a client or regulatory agency to know “for sure” that a test crew that shows up on a job site on a particular day is technically competent to perform the scope of work or that the equipment is adequate. Even if the testing company made the best decisions possible given the information at hand, the realities of field work are such that unexpected field conditions may thwart even the best laid plans. A client may be assured, however, that a company meeting the requirements of this standard has in place a system that minimizes quality problems and deals with them effectively when they do occur.

Does this mean it is never possible to evaluate the overall technical competence of a company? Not at all. A company may be considered "technically competent" if it consistently deploys the proper resources at the proper time...in other words, consistent performance over time. Competence is a function of performance over time. An adequate quality infrastructure fed with a representative sampling of performance over time is an excellent system for evaluating competence.

Part 1 - Scope

1.1 This document is a specific application of ISO 17025 to direct air emissions testing.

1.2 This standard applies to any source testing body engaging in air emissions testing required by an air permitting authority to:

a) demonstrate compliance with either an emission limit, or
b) establish conformance with air emission monitoring performance standards.

1.3 Accrediting Authorities wishing to include air emission testing within their NELAP authorized scope of accreditation must comply with the relevant sections of this standard.

1.4 A body subject to this standard is not subject to other standards or provisions established by the National Environmental Laboratory Accreditation Conference (NELAC) or the National Environmental Laboratory Accreditation Program (NELAP). This standard contains the complete requirements for establishing and assessing competence in the given scope under NELAC and NELAP.

Part 2 - Terms and Definitions

For the purposes of this standard, the terms and definitions given in ISO/IEC Guide 2 and VIM apply with the following changes and additions.

2.1 Air Emission Testing: The direct testing of emissions to the atmosphere by sampling, measurement and analysis including determination of the relative accuracy of continuous monitoring systems. This definition excludes fuel sampling, visible emission evaluations, and daily operation and maintenance of continuous monitoring systems.

2.2 Approved Test Protocol. A statement, approved by the relevant regulatory agency, of the objectives of a specific test program and the test methods (and deviations) to be used to achieve those objectives. Also referred to as “sampling plan” or “test plan”.

2.3 Laboratory: When the term “laboratory” is used to refer to the business entity conducting testing, substitute the term “testing body”. When the term “laboratory” refers to a physical space, it means the immediate area in which the testing activity is being performed.

2.4 Competence. A testing body shall be considered competent if it has in place and continually operates under a quality system meeting the requirements of this standard.

2.5 Known and Documented Data Quality. For the purposes of this application, data will be of known and documented quality if collected under a quality system meeting the requirements of this standard (including adherence to approved test protocols).

2.6 Quality System Problem. A quality system problem may be of two types:

1) Feedback from a relevant regulatory authority, customer, or internal assessor/auditor that some aspect of a test program or test data failed to meet expectations.

2) Feedback from an internal or external assessor/auditor that the testing body failed to follow its quality plan or that a required component of the plan is absent.

2.7 Reference Method. Any test method promulgated by US EPA or other relevant regulatory agency through public rulemaking.

Part 3 - Standard of Performance

The following is the standard of performance for testing bodies covered under the scope of this standard. The standard is presented in a two-column format. The first column presents the specific requirements of the standard. The second column presents information on how each requirement is to be assessed.

Note: The BLACK text is the exact language of ISO 17025
The RED text is language implementing this application or instructions on assessment

The following language applies to many sections of this standard. Rather than repeating it, each section to which it applies references it as "NOTE A" or "NOTE B" or both.

NOTE A - Conformance with this section shall be demonstrated with a statement of policy or procedures in the quality manual addressing this issue.

NOTE B - The assessor shall determine that stated policies, processes, or procedures are in place and by so doing, deem that the requirements of this section of the standard have been fulfilled unless a quality system problem is found whose root cause is determined to have originated from the requirements of this section.

Section 1 - Scope

As per ISO 17025 and modified by Part 1 of this document.

Section 2 - Normative References

As per ISO 17025

Section 3 - Definitions

As per ISO 17025 and modified by Part 2 of this document.

Section 4 - Management requirements

Standard of Performance	Assessment of Performance
4.1 Organization	
4.1.1 The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.	Conformance with this section shall be demonstrated with a state approved business license or registration.
4.1.2 It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the client, the regulatory authorities or organizations providing recognition.	Conformance with this section shall be demonstrated with a quality plan meeting the requirements of this standard.
4.1.3 The laboratory management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.	NOTE A The assessor shall assume that this statement is truthful and effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.
4.1.4 If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the laboratory shall be defined in order to identify potential conflicts of interest.	Conformance with this section shall be demonstrated with job descriptions of the relevant personnel and a written or verbal description of conflict of interest policy and procedures. NOTE B

NOTE 1 Where a laboratory is part of a larger organization, the organizational arrangements should be such that departments having conflicting interests, such as production, commercial marketing or financing do not adversely influence the laboratory's compliance with the requirements of this International Standard.

NOTE 2 if the laboratory wishes to be recognized as a third-party laboratory, it should be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory should not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

Standard of Performance	Assessment of Performance
4.1.5 The laboratory shall:	
a) have managerial and technical personnel with the authority, responsibility, and resources needed to carry out their duties and to identify the occurrence of departures from the quality system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);	Conformance with this section shall be demonstrated with an organizational chart of the company and job descriptions of the relevant positions. The assessor shall assume that personnel have adequate authority and resources to carry out required tasks unless a quality system problem is found whose root cause is relevant to the requirements of this section.
b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;	NOTE A NOTE B
c) have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;	Same as above
d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;	Same as above
e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;	Conformance with this section shall be demonstrated with an organizational chart of the company.
f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;	Conformance with this section shall be demonstrated with an organizational chart of the company and job descriptions of the relevant positions.

Standard of Performance	Assessment of Performance
Section 4.1.5 (con't)	
g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;	NOTE A NOTE B
h) have technical management which has overall authority and responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;	Conformance with this section shall be demonstrated with an organizational chart of the company and job descriptions of the relevant positions. The assessor shall assume that personnel have adequate authority and resources to carry out required tasks unless a quality system problem is found whose root cause is relevant to the requirements of this section.
i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority and resources for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;	Conformance with this section shall be demonstrated with an organizational chart of the company. The appointed staff member shall be identified by name on the chart. The assessor shall assume that this person has adequate authority and resources to carry out required tasks unless a quality system problem is found whose root cause is relevant to the requirements of this section.
j) appoint deputies for key managerial personnel (see note).	Conformance with this section shall be demonstrated with an organizational chart of the company. Whether or not deputies are appointed and the number of such deputies is at the discretion of the company. The assessor shall assume that this arrangement is effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.

Standard of Performance	Assessment of Performance
Section 4.1.5 (con't)	
k) have an ethics policy in place, signed by each employee involved in testing or calibration activities. The ethics policy shall define fraud and the ranges of consequences for engaging in fraudulent activity. The definition of fraud must include the omission of data or information from a test report (or supporting data) that has relevance to the test results or test result interpretation.	Conformance with this section shall be demonstrated by presenting the signed ethics policy statement.

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

Standard of Performance	Assessment of Performance
4.2 Quality system	
4.2.1 The laboratory shall establish, implement and maintain a quality system appropriate to the scope of its activities, The laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.	Conformance with this section shall be demonstrated with a quality manual meeting the requirements of this standard. The assessor shall assume that the policies and procedures contained in this manual including those addressing communication and implementation are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.
4.2.2 The laboratory's quality system policies and objectives shall be defined in a quality manual (however named). The overall objectives shall be documented in a quality policy statement. The quality policy statement shall be issued under the authority of the chief executive. it shall include at least the following:	Conformance with this section shall be demonstrated with a quality manual meeting the requirements of this standard. The assessor shall assume that the policies and procedures contained in this manual are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.
a) the laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its clients;	Same as above
b) the management's statement of the laboratory's standard of service;	Same as above
c) the objectives of the quality system;	Same as above

Standard of Performance	Assessment of Performance
4.2 Quality system (con't)	
d) a requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work;	Conformance with this section shall be demonstrated with a quality manual meeting the requirements of this standard. The assessor shall assume that the policies and procedures contained in this manual are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.
e) the laboratory management's commitment to compliance with this International Standard.	Same as above

APPLICATION NOTE See Appendix A of this standard for an example outline for a quality plan document.

NOTE The quality policy statement should be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and clients requirements. When the test and/or calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

Standard of Performance	Assessment of Performance
4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system.	Conformance with this section shall be demonstrated with a quality manual meeting the requirements of this standard.
4.2.4 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard; shall be defined in the quality manual.	Conformance with this section shall be demonstrated with a quality manual meeting the requirements of this standard.

Standard of Performance	Assessment of Performance
4.3 Document control	
4.3.1 General. The laboratory shall establish and maintain procedures to control all documents that form part of its quality system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.	NOTE A NOTE B

NOTE 1 In this context “document” could be policy statements, procedures, specifications, calibration tables, charts, textbooks, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analog, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.12.

Standard of Performance	Assessment of Performance
4.3 Document control (con’t)	
4.3.2 Document approval and issue	
4.3.2.1 All documents issued to personnel in the laboratory as part of the quality system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the quality system shall be established and be readily available to preclude the use of invalid and/or obsolete documents.	Conformance with this section shall be demonstrated with sign-off sheets showing receipt by each employee of the quality manual and any additions thereto. The sign-off sheet shall specify the version number of the quality manual and the date of receipt by each employee.

Standard of Performance	Assessment of Performance
4.3 Document control (con’t)	
4.3.2 Document approval and issue (con’t)	
4.3.2.2 The procedure(s) adopted shall ensure that:	
a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;	NOTE A NOTE B
b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;	Same as above
c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;	Same as above
d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.	Same as above

Standard of Performance	Assessment of Performance
4.3 Document control (con't)	
4.3.2 Document approval and issue (con't)	
4.3.2.2 (con't)	
4.3.2.3 Quality system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).	Conformance with this section shall be demonstrated by formatting the quality manual and any additions thereto as specified in this section.
4.3.3 Document changes	
4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.	NOTE A NOTE B
4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.	Same as above
4.3.3.3 If the laboratory's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.	Same as above
4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.	Same as above

Standard of Performance	Assessment of Performance
4.4 Review of requests, tenders and contracts	
4.4.1 The laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:	NOTE A NOTE B
a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);	Same as above
b) the laboratory has the capability and resources to meet the requirements;	Same as above
c) the appropriate test and/or calibration method is selected and capable of meeting the clients' requirements (see 5.4.2).	Same as above
Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the client.	Same as above

NOTE 1 The request, tender and contract review should be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects should be taken into account. For internal clients, reviews of requests, tenders and contracts can be performed in a simplified way.

NOTE 2 The review of capability should establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary for the performance of the tests and/or calibrations in question. The review may also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial test or calibration programmes using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

NOTE 3 A contract is an agreement, comprising form and content elements, reached between two parties that is consistent with the needs of the two parties. A contract may be any written or oral agreement to provide a client with testing and/or calibration services.

Standard of Performance	Assessment of Performance
4.4 Review of requests, tenders and contracts (con't)	
4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a client relating to the client's requirements or the results of the work during the period of execution of the contract.	Conformance with this section shall be demonstrated with a test protocol approved by the relevant regulatory agency. Client or agency correspondence, if available, shall supplement this conformance demonstration. The assessor shall assume that an approved test protocol along with any correspondence provides adequate assurance of conformance with this section unless a quality system problem is found whose root cause is relevant to the requirements of this section.

NOTE For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for on-going routine work performed under a general agreement with the client, provided that the client's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record should be maintained.

Standard of Performance	Assessment of Performance
4.4 Review of requests, tenders and contracts (con't)	
4.4.3 The review shall also cover any work that is subcontracted by the laboratory.	NOTE A NOTE B
4.4.4 The client shall be informed of any deviation from the contract.	Same as above.
4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.	Same as above.

Standard of Performance	Assessment of Performance
4.5 Subcontracting of tests and calibrations	
4.5.1 When a laboratory subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.	NOTE A NOTE B A competent sub-contractor is one who operates under the same quality system (or equivalent) as the testing body. If the sub-contractor is under the direct supervision and control of the testing body and operates under the same quality system, it is not necessary for the sub-contractor to be accredited to this standard.
4.5.2 The laboratory shall advise the client of the arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing.	Conformance with this section shall be demonstrated by listing the name of any subcontractor used either in the test protocol or the test report.
4.5.3 The laboratory is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.	This is an assignment of responsibility. No conformance demonstration is required.
4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.	Conformance with the subcontractor register requirement of this section shall be demonstrated by listing the name of any subcontractor used either in the test protocol or the test report. Conformance with the record of evidence requirement of this section shall be demonstrated with an agency approved test protocol and test report. The assessor shall assume that such records provide adequate assurance of compliance with this standard unless a quality system problem is found whose root cause is relevant to the requirements of this section.

Standard of Performance	Assessment of Performance
4.6 Purchasing services and supplies	
4.6.1 The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.6 Purchasing services and supplies (CON'T)	
4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.6 Purchasing services and supplies (con't)	
4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.	NOTE A NOTE B

NOTE The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data including approval of test results, the quality required and the quality system standard under which they were made.

Standard of Performance	Assessment of Performance
4.6 Purchasing services and supplies (con't)	
4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.7 Service to the client	
The laboratory shall afford clients or their representatives cooperation to clarify the client's request and to monitor the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other clients.	NOTE A NOTE B

NOTE 1 Such cooperation may include:

a) providing the client or the client's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the client;

b) preparation, packaging, and dispatch of test and/or calibration items needed by the client for verification purposes.

NOTE 2 Clients value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the client, especially in large assignments, should be maintained throughout the work. The laboratory should inform the client of any delays or major deviations in the performance of the tests and/or calibrations.

NOTE 3 Laboratories are encouraged to obtain other feedback, both positive and negative, from their clients (e.g. client surveys). The feedback should be used to improve the quality system, testing and calibration activities and client service.

Standard of Performance	Assessment of Performance
4.8 Complaints	
The laboratory shall have a policy and procedure for the resolution of complaints received from clients or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.10).	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.9 Control of nonconforming testing and/or calibration work	
4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policy and procedures shall ensure that:	NOTE A NOTE B
a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;	Same as above.
b) an evaluation of the significance of the nonconforming work is made;	Same as above.
c) corrective actions are taken immediately, together with any decision about the acceptability of the nonconforming work;	Same as above.
d) where necessary, the client is notified and work is recalled;	NOTE A NOTE B
e) the responsibility for authorizing the resumption of work is defined.	Same as above.

NOTE identification of nonconfoming work or problems with the quality system or with testing and/or calibration activities can occur at various places within the quality system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

Standard of Performance	Assessment of Performance
4.9 Control of nonconforming testing and/or calibration work (con't)	
4.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.10 shall be promptly followed.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.10 Corrective action	
4.10.1 General. The laboratory shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system or technical operations have been identified.	NOTE A NOTE B

NOTE A problem with the quality system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from clients or staff observations.

Standard of Performance	Assessment of Performance
4.10 Corrective action (con't)	
4.10.2 Cause analysis. The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	Conformance with this section shall be demonstrated by the presence of a root cause analysis requirement at the start of the corrective action procedure in the quality manual. NOTE B

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include client requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

Standard of Performance	Assessment of Performance
4.10 Corrective action (con't)	
4.10.3 Selection and implementation of corrective actions. Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	NOTE A The assessor shall assume that corrective actions selected and implemented are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless monitoring required in 4.10.4 provides evidence of ineffectiveness.

Standard of Performance	Assessment of Performance
4.10 Corrective action (con't)	
4.10.3 (con't) Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.	The assessor shall assume that any corrective action selected is appropriate unless a quality system problem is found whose root cause is relevant to the requirements of this section.
The laboratory shall document and implement any required changes resulting from corrective action investigations.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.10 Corrective action (con't)	
4.10.4 Monitoring of corrective actions. The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.	NOTE A NOTE B
4.10.5 Additional audits. Where the identification of nonconformances or departures casts doubts on the laboratory's compliance with its own policies and procedures, or on its compliance with this International Standard, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.13 as soon as possible.	Same as above.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit should be necessary only when a serious issue or risk to the business is identified.

Standard of Performance	Assessment of Performance
4.11 Preventive action	
4.11.1 Needed improvements and potential sources of nonconformances, either technical or concerning the quality system, shall be identified. If preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformances and to take advantage of the opportunities for improvement.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
4.11 Preventive action (con't)	
4.11.2 Procedures for preventive actions shall include the initiation of such actions and application of controls to ensure that they are effective.	NOTE A NOTE B

APPLICATION NOTE Many testing bodies, especially smaller ones, have informal procedures for preventative actions. Unless found deficient due to a quality system problem whose root cause can be traced back to an inefficient preventative action program, the assessor shall assume that any informal preventative action program practiced by the testing body meets the requirements of this section.

NOTE 1 Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.
NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

Standard of Performance	Assessment of Performance
4.12 Control of records	
4.12.1 General	
4.12.1 .l The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.	NOTE A The assessor shall assume that the policies and procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless during an investigation related to an identified quality system problem the assessor finds that such procedures are inadequate for a complete investigation.
4.12.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.	Same as above.

NOTE Records may be in any media, such as hard copy or electronic media.

Standard of Performance	Assessment of Performance
4.12 Control of records (con't)	
4.12.1 General (con't)	
4.12.1.3 All records shall be held secure and in confidence.	NOTE A The assessor shall assume that the policies and procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless during an investigation related to an identified quality system problem the assessor finds that such procedures are inadequate for a complete investigation.

Standard of Performance	Assessment of Performance
4.12 Control of records (con't)	
4.12.1 General (con't)	
4.12.1.4 The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	NOTE A The assessor shall assume that the policies and procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless during an investigation related to an identified quality system problem the assessor finds that such procedures are inadequate for a complete investigation.
4.12.2 Technical records	
4.12.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.	Same as above. Note: To demonstrate conformance with the identification of factors requirement, relevant operating data from the source must be included with the test report, when available.

NOTE 1 In certain fields it may be impossible or impractical to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, clients' notes, papers and feedback.

Standard of Performance	Assessment of Performance
4.12 Control of records (con't)	
4.12.2 Technical records (con't)	
4.12.2.2 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	NOTE A The assessor shall assume that the policies and procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless during an investigation related to an identified quality system problem the assessor finds that such procedures are inadequate for a complete investigation of that problem.
4.12.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction. In the case of records stored ,electronically, equivalent measures shall be taken to avoid loss or change of original data.	Same as above.

Standard of Performance	Assessment of Performance
4.13 Internal audits	
4.13.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and this International Standard. The internal audit programme shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.	Conformance with this section shall be demonstrated with internal audit reports. The assessor shall assume that such reports are complete and accurate and that the personnel conducting the audits are adequately trained and qualified unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless during an investigation related to an identified quality system problem the assessor finds that such assumptions do not allow for a complete investigation of that problem. An internal audit may be combined with a management audit conducted in accordance with Section 4.14 and reported together.

NOTE The cycle for internal auditing should normally be completed in one year.

Standard of Performance	Assessment of Performance
4.13 Internal audits (con't)	
4.13.2 When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the laboratory's test or calibration results, the laboratory shall take timely corrective action, and shall notify clients in writing if investigations show that the laboratory results ~~may~~ have been affected.	Conformance with this section shall be demonstrated with a statement of policy or procedures in the quality manual addressing this issue. The assessor shall assume that the policies and procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section or unless during an investigation related to an identified quality system problem the assessor finds that such procedures are inadequate for a complete investigation of that problem.
4.13.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.	Same as above
4.13.4 Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.	Same as above

Standard of Performance	Assessment of Performance
4.14 Management reviews	
4.14.1 In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of: - the suitability of policies and procedures; - reports from managerial and supervisory personnel; - the outcome of recent internal audits; - corrective and preventive actions; - assessments by external bodies; - the results of inter-laboratory comparisons or proficiency tests; - changes in the volume and type of the work; - client feedback; - complaints; - other relevant factors, such as quality control activities, resources and staff training.	NOTE A A management review may be combined with an internal audit conducted in accordance with Section 4.13. and reported together.

NOTE 1 A typical period for conducting a management review is once every 12 months.

NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.

NOTE 3 A management review includes consideration of related subjects at regular management meetings.

Standard of Performance	Assessment of Performance
4.14 Management reviews (con't)	
4.14.2 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.	NOTE A NOTE B

Section 5 - Technical requirements

APPLICATION NOTE Language in this Section pertaining to calibration laboratories is not applicable to testing bodies covered by this standard.

Standard of Performance	Assessment of Performance
5.1 General	
5.1.1 Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from: - human factors (5.2), - accommodation and environmental conditions (5.3), - test and calibration methods and method validation (5.4), - equipment (5.5), - measurement traceability (5.6), - sampling (5.7), - Handling of test and calibration items (5.8).	This is a general statement identifying potential sources of measurement. No conformance demonstration is required.
5.1.2 The extent to which the factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.	Conformance with this section shall be demonstrated by following approved test protocols for all tests performed and by following the testing body's stated training policy or procedure. NOTE B

Standard of Performance	Assessment of Performance
5.2 Personnel	
5.2.1 The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as required.	Conformance with this section shall be demonstrated by following the testing body's stated training policy or procedures. NOTE B

NOTE 1 In some technical areas (e.g. non-destructive testing) it may be required that the personnel performing certain tasks hold personnel certification. The laboratory is responsible for fulfilling specified personnel certification requirements. The requirement for personnel certification might be regulatory, included in the standards for the specific technical field, or required by the client.

NOTE 2 The personnel responsible for the opinions and interpretation included in test reports should, in addition to appropriate qualification, training, experience and satisfactory knowledge of the testing carried out, also have:

- relevant understanding of the technology used for the manufacturing of the items, materials, products, etc. or the way they are used, or intended to be used, and of the defects or degradations which may occur during or in service;
- knowledge of the general requirements expressed in the legislation or general standards;
- and an understanding of the significance of the deviations found with regard to the normal use of the items, materials, products, etc. concerned.

Standard of Performance	Assessment of Performance
5.2 Personnel (con't)	
5.2.2 The management of the laboratory shall formulate the goals with respect to the education, training and skills of the laboratory personnel. The laboratory shall have a policy and procedures for identifying training needs and providing training to personnel. The training programme shall be relevant to the present and anticipated tasks of the laboratory.	Conformance with this section shall be demonstrated by following the testing body's stated training policy or procedures. NOTE B
5.2.3 The laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's quality system.	Conformance with this section shall be demonstrated by following the testing body's stated supervision policy or procedures. NOTE B
5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.	Conformance with this section shall be demonstrated by providing job descriptions as stated. Personnel affected by this section shall be as defined by the testing body. See Notes.

APPLICATION NOTE Job descriptions need not be linked to specific individuals, but may be developed for categories of jobs performed (i.e. crew leader, technician, etc).

NOTE Job descriptions can be defined in many ways. As a minimum, the following should be defined:

- the responsibilities with respect to performing tests and/or calibrations;
- the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;
- the responsibilities for reporting opinions and interpretations;
- the responsibilities with respect to method modification and development and validation of new methods;
- expertise and experience required;
- qualifications and training programmes;
- managerial duties.

APPLICATION NOTE: For the purposes of this application, the note above shall be replaced with the following:

Job descriptions are dependent on a company's operational model and for that reason can be defined in many ways. A company should consider identifying key functions within its operations and writing job descriptions that convey the duties, responsibilities, authorities, and expertise (i.e., experience, education, and or training) of an individual performing the required function.

Standard of Performance	Assessment of Performance
5.2 Personnel (con't)	
5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorizations(s), competence, educational and professional qualifications, training, skills and experience of al technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.	Conformance with this section shall be demonstrated by following the testing body's stated policy or procedures on authorizations and demonstrations of competence. NOTE B

NOTE The term "contracted personnel" includes only personnel not directly employed by the testing body but under the direct supervision of the testing body. It is not necessary to maintain records for personnel employed by and supervised by outside contractors or sub-contractors.

Standard of Performance	Assessment of Performance
5.3 Accommodation and environmental conditions	
5.3.1 Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.	Conformance with this section shall be demonstrated by documenting relevant environmental conditions and any accommodations to those conditions in the test report. The assessor shall assume that such documentation and accommodation provides assurance of adequate testing conditions unless a quality system problem is found whose root cause is relevant to the requirements of this section.

APPLICATION NOTE In many cases, the environmental conditions under which a stack test takes place are not under the control of the testing body. Any conditions that occur during the test that affect data quality shall be documented in the test report.

Standard of Performance	Assessment of Performance
5.3 Accommodation and environmental conditions (con't)	
5.3.1 (con't)	
The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Particular care shall be taken when sampling and tests and/or calibrations are undertaken at sites other than a permanent laboratory facility. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.	Conformance with this section shall be demonstrated by documenting relevant environmental conditions and any accommodations to those conditions in the test report. The assessor shall assume that such documentation and accommodation provides assurance of adequate testing conditions unless a quality system problem is found whose root cause is relevant to the requirements of this section.
5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.	Same as above.

APPLICATION NOTE It is the responsibility of the testing body to inform the client of the possible effects of environmental conditions on data quality. The decision to stop a test due to environmental effects rests with the client or regulatory authority unless the conditions pose a safety threat to personnel performing the test, in which case, the testing body shall have the authority to abort the test.

Standard of Performance	Assessment of Performance
5.3 Accommodation and environmental conditions (con't)	
5.3.3 There shall be effective separation between neighboring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.	NOTE A NOTE B
5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The laboratory shall determine the extent of control based on its particular circumstances.	Same as above
5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.	The assessor shall assume that any housekeeping measures taken are adequate unless a quality system problem is found whose root cause is relevant to the requirements of this section.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation	

APPLICATION NOTE Methods for stack testing are currently defined by applicable regulations. Alternatives or deviations from these methods shall be detailed in the test protocol and/or the test report along with any authorizations for the alternatives or deviations..

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.1 General	
The laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.	Conformance with this section shall be demonstrated by following approved test protocols for all testing. The assessor shall assume that such protocols are appropriate and effective unless a quality system problem is found whose root cause is relevant to the requirements of this section. Estimates of uncertainty beyond those required by the test methods are not required when following an approved test protocol.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.1 General (con't)	
The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibration. All instruction, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3). Deviation from test and calibration method shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.	NOTE A NOTE B

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.2 Selections of methods	
The laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests and/or calibrations it undertakes. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriated or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.	Conformance with this section shall be demonstrated by following approved test protocols for all tests. The assessor shall assume that such protocols are appropriate and effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.2 Selections of methods (con't)	
When the client does not specify the method to be used, the laboratory shall select appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment.	Conformance with this section shall be demonstrated by following approved test protocols for all tests. The assessor shall assume that such protocols are appropriate and effective unless a quality system problem is found whose root cause is relevant to the requirements of this section. When the client does not specify methods to be used, the testing body shall consult with the appropriate regulatory agency and/or review any relevant permit conditions before selecting test methods.
The laboratory shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.	NOTE A NOTE B
5.4.3 Laboratory-developed methods	
The introduction of test and calibration methods developed by the laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.	Same as above
Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.	Same as above.
5.4.4 Non-standard methods	
When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and shall include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.	Conformance with this section shall be demonstrated with a statement of policy or procedures in the quality manual addressing this issue. The assessor shall assume that such policies or procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.

NOTE For new test and/or calibration methods, procedures should be developed prior to the tests and/or calibrations being performed and should contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the type of item to be tested or calibrated;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure, including affixing of identification marks, handling, transporting, storing and preparation of items, checks to be made before the work is started, checks that the equipment is working properly and, where required, calibration and adjustment, of the equipment before each use, the method of recording the observations and results, and any safety measures to be observed;

i) criteria and/or requirements for approval/rejection;

j) data to be recorded and method of analysis and presentation;

k) the uncertainty or the procedure for estimating uncertainty.

APPLICATION NOTE: For the purpose of this application, the above note is deleted and replaced with the following:

When it is necessary for a testing body to perform test methods which it has not performed, but which are established, published, or validated test methods, the testing body must take appropriate actions to ensure that the applicable requirements of Section 5 are properly addressed before and during the performance of the new method.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.5 Validation of Methods	
5.4.5.1 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.	This is a definition. No conformance demonstration is required.
5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.	Conformance with this section shall be demonstrated by following approved test protocols for all tests. The assessor shall assume that such protocols are sufficiently validated unless a quality system problem is found whose root cause is relevant to the requirements of this section.

NOTE 1 Validation may include procedures for sampling, handling and transportation.

NOTE 2 The techniques used for the determination of the performance of a method should be one of, or a combination of, the following: calibration using reference standards or reference materials; comparison of results achieved with other methods; interlaboratory comparisons; systematic assessment of the factors influencing the result; assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

NOTE 3 When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

APPLICATION NOTE For the purpose of this application the three notes above are deleted and replaced with the following:

EPA Method 301 sets forth the requirements of method validation as it relates to air emission testing for demonstration of compliance with air emission testing programs governed by Federal regulations. Regulatory agencies and source testing agencies may find this method useful when developing and validating new test methods or validating the effectiveness of an existing test method on a new source.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.5 Validation of Methods (con't)	
5.4.5.3 The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the clients' needs.	Conformance with this section shall be demonstrated by following approved test protocols for all tests. The assessor shall assume that such protocols are appropriate and effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.

NOTE 1 Validation includes specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

NOTE 2 As method-development proceeds, regular review should be carried out to verify that the needs of the client are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

NOTE 3 Validation is always a balance between costs, risks and technical possibilities. There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit,

selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.6 Estimation of uncertainty of measurement	
5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement of all calibration and types of calibrations.	Conformance with this section shall be demonstrated by use of approved test protocols for all tests. When such protocols are used, explicit statements of uncertainty, are not required.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.6 Estimation of uncertainty of measurement (con't)	
5.4.6.2 Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example previous experience and validation data.	Conformance with this section shall be demonstrated by use of approved test protocols for all tests. When such protocols are used, explicit statements of uncertainty, are not required.

NOTE 1 The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- the requirements of the test method;
- the requirements of the client;
- the existence of narrow limits on which decisions on conformance to a specification are based.

NOTE 2 In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.6 Estimation of uncertainty of measurement (con't)	
5.4.6.3 When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.	Conformance with this section shall be demonstrated by use of approved test protocols for all tests. When such protocols are used, explicit statements of uncertainty, are not required.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information; see ISO 5725 and the Guide to the Expression of Uncertainty in Measurement (see bibliography).

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.7 Control of Data	
5.4.7.1 Calculations and data transfers shall be subject to appropriate checks in a systematic manner.	NOTE A NOTE B
5.4.7.2 When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:	Same as above
a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;	Same as above.
b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, date transmission and data processing;	Same as above.

Standard of Performance	Assessment of Performance
5.4 Test and calibration methods and method validation (con't)	
5.4.7 Control of Data (con't)	
c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.	Same as above.

NOTE Commercial off-the-shelf software (e.g. word processing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/ modifications should be validated as in 5.4.7.2a).

Standard of Performance	Assessment of Performance
5.5 Equipment	
5.5.1 The laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this International Standard are met.	"Furnished" shall be defined as being owned by or available to the test body. NOTE A NOTE B
5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being place into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).	NOTE A NOTE B

Standard of Performance	Assessment of Performance
5.5 Equipment (con't)	
5.5.3 Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.	Same as above.
5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.	Same as above.
5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibration performed. The records shall include at least the following:	This section requires the testing body to maintain records on the calibration, maintenance and tracking of its equipment. These records should also address equipment not under the permanent control of the testing body (i.e. rental equipment). Records shall be adequate to: 1) ensure the equipment meets the requirements of this standard, 2) facilitate proper operation and maintenance, and 3) facilitate problem investigation and corrective action. Sections 5.5.5(a)-(f) shall be considered examples of records that meet this requirement for stack testing, but shall not be required in this application of ISO 17025.
a) the identity of the item of equipment and its software;	See above
b) the manufacturer's name, type identification, and serial number or other unique identification;	See above
c) checks that equipment complies with the specification (see 5.5.2);	See above
d) the current location, where appropriate;	See above
e) the manufacturer's instructions, if available, or reference to their location;	See above
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of the next calibration;	See above

Standard of Performance	Assessment of Performance
5.5 Equipment (con't)	
5.5.5 (con't)	
g) the maintenance plan, where appropriate, and maintenance carried out to date;	See above
h) any damage, malfunction, modification or repair to the equipment.	See above
5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.	NOTE A NOTE B

NOTE Additional procedures may be necessary when measuring equipment is used outside the permanent laboratory for tests, calibrations or sampling.

Standard of Performance	Assessment of Performance
5.5 Equipment (con't)	
5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the 'Control of nonconforming work' procedure (see 4.9).	NOTE A NOTE B
5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.	Same as above.
5.5.9 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.	Same as above.

Standard of Performance	Assessment of Performance
5.5 Equipment (con't)	
5.5.10 When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.	NOTE A NOTE B
5.5.11 Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.	Same as above.
5.5.12 Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	Same as above.

Standard of Performance	Assessment of Performance
5.6 Measurement traceability	

APPLICATION NOTE Equipment modified, calibrated and maintained as described in the appropriate test method (e.g. EPA Reference Method) shall meet the requirements of this section. When standard methods are not used, the testing body shall calibrate equipment in accordance with this section.

Standard of Performance	Assessment of Performance
5.6 Measurement traceability	
5.6.1 General	
All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.	NOTE A NOTE B

NOTE Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

Standard of Performance	Assessment of Performance
5.6 Measurement traceability (con't)	
5.6.2 Specific requirements	
5.6.2.1 Calibration	
5.6.2.1.1 For calibration laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the International System of Units (SI) (Systeme International units). A calibration laboratory establishes traceability of its own measurement standards and measuring instruments to the SI by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurement. The link to SI units may be achieved by reference to national measurement standards. National measurement standards may be primary standards, which are primary realizations of the SI units or agreed representations of SI units based on fundamental physical constants, or they may be secondary standards which are standards calibrated by another national metrology institute. When using external calibration services, traceability of measurement shall be assured by the use of calibration services from laboratories that can demonstrate competence, measurement capability and traceability. The calibration certificates issued by these laboratories shall contain the measurement results, including the measurement uncertainty and/or a statement of compliance with an identified metrological specification (see also 5.10.4.2).	This section does not apply to testing bodies. No conformance demonstration is required.

NOTE 1 Calibration laboratories fulfilling the requirements of this International Standard are considered to be competent. A calibration certificate bearing an accreditation body logo from a calibration laboratory accredited to this International Standard, for the calibration concerned, is sufficient evidence of traceability of the calibration data reported.

NOTE 2 Traceability to SI units of measurement may be achieved by reference to an appropriate primary standard (see VlM:1993, 6.4) or by reference to a natural constant, the value of which in

terms of the relevant SI unit is known and recommended by the General Conference of Weights and Measures (CGPM) and the International Committee for Weights and Measures (ClPM).

NOTE 3 Calibration laboratories that maintain their own primary standard or representation of SI units based on fundamental physical constants can claim traceability to the SI system only after these standards have been compared, directly or indirectly, with other similar standards of a national metrology institute.

NOTE 4 The term 'identified rnetrological specification' means that it must be clear from the calibration certificate which specification the measurements have been compared with, by including the specification or by giving an unambiguous reference to the specification.

NOTE 5 When the terms 'international standard' or 'national standard' are used in connection with traceability, it is assumed that these standards fulfill the properties of primary standards for the realization of SI units.

NOTE 6 Traceability to national measurement standards does not necessarily require the use of the national metrology institute of the country in which the laboratory is located.

NOTE 7 If a calibration laboratory wishes or needs to obtain traceability from a national rnetrology institute other than in its own country, this laboratory should select a national metrology institute that actively participates in the activities of BIPM either directly or through regional groups.

NOTE 8 The unbroken chain of calibrations or comparisons may be achieved in several steps carried out by different laboratories that can demonstrate traceability.

Standard of Performance	Assessment of Performance
5.6 Measurement traceability (con't)	
5.6.2 Specific requirements (con't)	
5.6.2.1 Calibration (con't)	
5.6.2.1.2 There are certain calibrations that currently cannot be strictly made in SI units. In these cases calibration shall provide confidence in measurements by establishing traceability to appropriate measurement standards such as: the use of certified reference materials provided by a competent supplier to give a reliable physical or chemical characterization of a material; the use of specified methods and/or consensus standards that are clearly described and agreed by all parties concerned. Participation in a suitable programme of interlaboratory comparisons is required where possible.	This section does not apply to testing bodies. No conformance demonstration is required.

Standard of Performance	Assessment of Performance
5.6 Measurement traceability (con't)	
5.6.2 Specific requirements (con't)	
5.6.2.2 Testing	
5.6.2.2.1 For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.	Conformance with this section shall be demonstrated by following the calibration procedures specified in an approved test protocol.

NOTE The extent to which the requirements in 5.6.2.1 should be followed depends on the relative contribution of the calibration uncertainty to the total uncertainty. If calibration is the dominant factor, the requirements should be strictly followed.

Standard of Performance	Assessment of Performance
5.6 Measurement traceability (con't)	
5.6.2 Specific requirements (con't)	
5.6.2.2 Testing (con't)	
5.6.2.2.2 Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories (see 5.6.2.1.2).	Conformance with this section shall be demonstrated by following the calibration procedures specified in an approved test protocol.
5.6.3 Reference standards and reference materials	
5.6.3.1 Reference standards	
The laboratory shall have a programme and procedure for the calibration of its reference standards. Reference standards shall be calibrated by a body that can provide traceability as described in 5.6.2.1. Such reference standards of measurement held by the laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated. Reference standards shall be calibrated before and after any adjustment.	NOTE A NOTE B

Standard of Performance	Assessment of Performance
5.6 Measurement traceability (con't)	
5.6.3 Reference standards and reference materials (con't)	
5.6.3.2 Reference materials	
Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.	NOTE A NOTE B
5.6.3.3 Intermediate checks	
Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules	Same as above.
5.6.3.4 Transport and storage	
The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.	Same as above.

NOTE Additional procedures may be necessary when reference standards and reference materials are used outside the permanent laboratory for tests, calibrations or sampling.

Standard of Performance	Assessment of Performance
5.7 Sampling	
5.7.1 The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. The sampling process shall address the factors to be controlled to ensure the validity of the test and calibration results.	For the purpose of this application, the term "sampling plan" shall be defined as a site-specific test plan or test protocol. It shall include any information necessary for a full and complete understanding of the test project. This may include, but is not limited to, test project objectives, test methods, approved method alterations or deviations, QA/QC procedures, process descriptions, description of test locations, analytical procedures, and other relevant information. Relevant information need not be copied directly into the test plan but may be incorporated by reference (e.g. Reference Methods, internal QA/QC procedures). Conformance with this section shall be demonstrated with approved test protocols for all testing. The assessor shall assume that such protocols are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.

APPLICATION NOTE 1 The test plan shall be the primary source of information on testing and quality procedures for the test project. It is the document against which an assessor shall perform the on-site assessment. The contents of this plan shall be communicated to all personnel participating in the test project prior to the start of the project.

APPLICATION NOTE 2 It is recommended that testing bodies adopt a standard test plan format and that this format follow examples provided by regulatory authorities. Examples of test plan contents and formats may be found in EPA Guideline Document GD-042, "Preparation and Review of Site-Specific Emission Test Plans" and in 40 CFR 63.7.

NOTE 1 Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole. Sampling may also be required by the appropriate specification for which the substance, material or product is to be tested or calibrated, in certain cases (e.g. forensic analysis), the sample may not be representative but is determined by availability.

NOTE 2 Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or samples from a substance, material or product to yield the required information.

Standard of Performance	Assessment of Performance
5.7 Sampling (con't)	
5.7.2 Where the client requires deviations, additions or exclusions from the documented sampling procedure, these shall be recorded in detail with the appropriate sampling data and shall be included in all documents containing test and/or calibration results, and shall be communicated to the appropriate personnel.	NOTE A NOTE B
5.7.3 The laboratory shall have procedures for recording relevant data and operations relating to sampling that forms part of the testing or calibration that is undertaken. These records shall include the sampling procedure used, the identification of the sampler, environmental conditions (if relevant) and diagrams or other equivalent means to identify the sampling location as necessary and, if appropriate, the statistics the sampling procedures are based upon.	Same as above.

Standard of Performance	Assessment of Performance
5.8 Handling of test and calibration items	
5.8.1 The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including ail provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the client.	NOTE A NOTE B
5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory.	Same as above.

Standard of Performance	Assessment of Performance
5.8 Handling of test and calibration items (con't)	
5.8.3 Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the laboratory shall consult the client for further instructions before proceeding and shall record the discussion.	NOTE A NOTE B
5.8.4 The laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held secure, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.	Same as above.

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

NOTE 2 A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, should be provided to those responsible for taking and transporting the samples.

NOTE 3 Reasons for keeping a test or calibration item secure can be for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

Standard of Performance	Assessment of Performance
5.9 Assuring the quality of test and calibration results	
The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:	Conformance with this section shall be demonstrated by following approved test protocols for all tests and with a statement of policy or procedures in the quality manual addressing this issue. The assessor shall assume that such protocols, policies or procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.
a) regular use of certified reference materials and/or internal quality control using secondary reference materials;	Same as above.
b) participation in interlaboratory comparison or proficiency-testing programmes;	Same as above.
c) replicate tests or calibrations using the same or different methods;	Same as above.
d) retesting or recalibration of retained items;	Same as above.
e) correlation of results for different characteristics of an item.	Same as above.

NOTE The selected methods should be appropriate for the type and volume of the work undertaken.

APPLICATION NOTE The items in Sections 5.9(a)-(e) are primarily designed for fixed analytical chemistry laboratories. These activities may be difficult or impossible to perform under the scope of work covered by this standard (i.e. stack testing). While some evidence of these activities may be present in testing bodies subject to this standard, it is expected that they will not occur as often as in laboratories.

Standard of Performance	Assessment of Performance
5.10 Reporting the results	

APPLICATION NOTE In order to facilitate review, testing bodies are encouraged to follow standard reporting formats provided by regulatory agencies. An example of a reporting format can be found in EPA Guideline Document GD-043 “Preparation and Review of Emission Test Reports.”

Standard of Performance	Assessment of Performance
5.10 Reporting the results	
5.10.1 General	
The results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.	Conformance with this section shall be demonstrated with the testing body's test report and with a statement of policy or procedures in the quality manual addressing this issue. The assessor shall assume that such reports, policies or procedures are effective unless a quality system problem is found whose root cause is relevant to the requirements of this section.
The results shall be reported, usually in a test report or a calibration certificate (see note 1), and shall include all the information requested by the client and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.10.2, and 5.10.3 or 5.10.4.	Same as above.
In the case of tests or calibrations performed for internal clients, or in the case of a written agreement with the client, the results may be reported in a simplified way. Any information listed in 5.10.2 to 5.10.4 which is not reported to the client shall be readily available in the laboratory which carried out the tests and/or calibrations.	Same as above.

NOTE 1 Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.

NOTE 2 The test reports or calibration certificates may be issued as hard copy or by electronic data transfer provided that the requirements of this International Standard are met.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.2 Test reports and calibration certificates	
Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so:	Conformance with this section shall be demonstrated with the testing body's test report.
a) a title (e.g. 'Test Report' or 'Calibration Certificate');	Same as above.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.2 Test reports and calibration certificates (con't)	Conformance with this section shall be demonstrated with the testing body's test report.
b) the name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;	Same as above.
c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;	Same as above.
d) the name and address of the client;	Same as above.
e) identification of the method used;	Same as above.
f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;	Same as above.
g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;	Same as above.
h) reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;	Same as above.
i) the test or calibration results with, where appropriate, the units of measurement;	Same as above.
j) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;	Same as above.
k) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.	Same as above.

NOTE 1 Hard copies of test reports and calibration certificates should also include the page number and total number of pages.

NOTE 2 It is recommended that laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full, without written approval of the laboratory.

APPLICATION NOTE For the purpose of this application, NOTE 2 above shall be deleted and replaced with the following:

It is recommended that the testing body include a statement specifying that reproducing portions of the test report may omit critical substantiating documentation or be taken out of context and that due care must be exercised in this regard.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.3 Test reports	
5.10.3.1 In addition to the requirements listed in 5.10.2, test reports shall, where necessary for the interpretation of the test results, include the following:	
a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;	Conformance with this section shall be demonstrated with the testing body's test report.
b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;	Conformance with this section shall be demonstrated by a written statement in the test report confirming the testing body's compliance with the test plan and any authorized deviations.
c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a client's instruction so requires, or when the uncertainty affects compliance to a specification limit;	Conformance with this section shall be demonstrated by use of approved test protocols for all tests. When such protocols are used, explicit statements of uncertainty, are not required.
d) where appropriate and needed, opinions and interpretations (see 5.10.5);	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.
e) additional information which may be required by specific methods, clients or groups of clients.	Same as above.

APPLICATION NOTE Stack testing is a process that integrates sampling and analysis. The operating parameters of the source are often important for a complete and accurate interpretation of test results. Testing bodies, whenever possible, should incorporate information on relevant

source process parameters (e.g. raw material feed rates, steam flow, etc.) measured during the testing period.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.3 Test reports (con't)	
5.10.3.2 In addition to the requirements listed in 5.10.2 and 5.10.3.1, test reports containing the results of sampling shall include the following, where necessary for the interpretation of test results:	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.
a) the date of sampling;	Same as above.
b) unambiguous identification of the substance, material or product sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);	Same as above.
c) the location of sampling, including any diagrams, sketches or photographs;	Same as above.
d) a reference to the sampling plan and procedures used;	Same as above.
e) details of any environmental conditions during sampling that may affect the interpretation of the test results;	Same as above.
f) any standard or other specification for the sampling method or procedure, and deviations, additions to or exclusions from the specification concemed.	Same as above.
5.10.4 Calibration certificates	
5.10.4.1 In addition to the requirements listed in 5.10.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.
a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;	Same as above.
b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;	Same as above.
c) evidence that the measurements are traceable (see note 2 in 5.6.2.1.1).	Same as above.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.4 Calibration certificates (con't)	
5.10.4.2 The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.
When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.	Same as above.
When statements of compliance are made, the uncertainty of measurement shall be taken into account.	Same as above.
5.10.4.3 When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.	Same as above.
5.10.4.4 A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.	Same as above.
5.10.5 Opinions and interpretations	
When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.	Same as above.

NOTE 1 Opinions and interpretations should not be confused with inspections and product certifications as intended in ISO/IEC 17020 and ISO/IEC Guide 65.

NOTE 2 Opinions and interpretations included in a test report may comprise, but not be limited to, the following: an opinion on the statement of compliance/noncompliance of the results with requirements; fulfilment of contractual requirements; recommendations on how to use the results; guidance to be used for improvements.

NOTE 3 In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the client. Such dialogue should be written down.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.6 Testing and calibration results obtained from subcontractors	
When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.
When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.	Same as above.
5.10.7 Electronic transmission of results	
In the case of transmission of test or calibration results by telephone, telex, facsimile or other electronic or electromagnetic means, the requirements of this International Standard shall be met (see also 5.4.7).	Same as above.
5.10.8 Format of reports and certificates	
The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.	Same as above.

NOTE 1 Attention should be given to the lay-out of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

NOTE 2 The headings should be standardized as far as possible

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.9 Amendments to test reports and calibration certificates	
Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report [or Calibration Certificate], serial number ... [or as otherwise identified]", or an equivalent form of wording.	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.
Such amendments shall meet all the requirements of this International Standard.	Same as above.

Standard of Performance	Assessment of Performance
5.10 Reporting the results (con't)	
5.10.9 Amendments to test reports and calibration certificates (con't)	
When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.	Conformance with this section shall be demonstrated with the testing body's test report. Appropriateness and need shall be determined by the testing body.

Part 4 - Accreditation System

To be developed